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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/249,350	02/11/1999	WILLIAM G. TATTON	WTZ-004	9825

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EXAMINER	
BAHAR, MOJDEH	

ART UNIT	PAPER NUMBER
1617	25

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N. 09/249,350	Applicant(s) TATTON ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment and remarks in response to the office action of June 17, 2002 are acknowledged. Applicant's remarks are persuasive to remove the rejection under 35 USC 112 in the previous office action.

Newly added claims 30-31 are herein examined on the merits in so far as they read on the elected compound specie, desmethyldeprenyl, and the elected viral infection, HIV. Claims 1-8 and 30-31 are herein examined on the merits in so far as they read on the elected compound and viral infection species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tatton et al. (WO 97/28791, reference D1 in the IDS filed December 13, 1999) in view of Meulen et al. (DE 19708461; English abstract provided, reference D2 in the IDS filed December 13, 1999) and Tatton et al. (Neurology, 1996, reference CB in the IDS filed June 21, 1999), of record in the previous office action.

Tatton et al. (WO 97/28791) teaches a method of using deprenyl compounds in general and (-)-desmethyldeprenyl in particular to treat viral infections, (page 9, lines 15-20 and page 10, lines 25-26). Tatton et al. (WO 97/28791) also teaches a pharmaceutically acceptable carrier

(page 15, lines 5-20) as well as transdermal patches as a method of administering (-)-desmethyldeprenyl (page 19, lines 17-25).

Tatton et al. (WO 97/28791) does not expressly teach the employment of (-)-desmethyldeprenyl particularly, in a method of treating HIV. Neither does it teach the treatment of a viral invention through the inhibition of virus replication.

Meulen et al. (DE 19708461) teaches a method of treating viral infections of the central nervous system employing D-Methyl Seligilin (a deprenyl compound), see abstract. Meulen et al. (DE 19708461) also teaches HIV as of one of the infections in which the method would be effective, Col. 1, lines 51-55.

Tatton et al. teaches a method of using (-)-desmethyldeprenyl as a mediator of antiapoptotic action, see abstract, page 171. Tatton et al. also teaches that AIDS Protein has been shown to induce apoptosis (p174 col.2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use (-)-desmethyldeprenyl, a known antiapoptotic agent, in the treatment of HIV viral infection since HIV protein is known to induce apoptosis.

One of ordinary skill in the art would have been motivated to use the deprenyl compound, (-)-desmethyldeprenyl in the treatment of HIV because (1) it is a known antiapoptotic agent and (2) is suggested to have antiviral activity. Given that AIDS protein has been known to induce apoptosis, an antiapoptotic agent would be useful in antagonizing the AIDS (HIV) virus protein activity. Moreover, the Skilled Artisan would have been motivated to employ a compound that is suggested to have antiviral activity broadly in a method of treating the HIV viral infection in particular, absent evidence to the contrary. No such evidence is seen. Note that the treatment of

a viral infection through the inhibition of virus replication is seen to be a mere recitation of the mechanism of action of the claimed method. Further, note that recitation of a mechanism of action by itself, will not patentably distinguish the claimed invention from the prior art which clearly suggests the usefulness of the elected compound herein in a method of treatment for HIV infection.

Response to Arguments

In the remarks submitted September 23, 2003, applicants argue that the cited prior art does not teach, nor suggests "a method of treating HIV by inhibition of virus replication by decreasing the infinity of GAPDH for viral RNA". Applicant's argument in this regard has been considered but is not persuasive. Applicant's argument is based on the mechanism of antiviral action herein. The underlined portion, "by inhibition of virus replication by decreasing the infinity of GAPDH for viral RNA", indicates nothing more than the mechanism of action through which viral replication is inhibited. The recitation of the mechanism of action by itself will not patentably distinguish the instant invention from the cited prior art which clearly suggests antiviral anti-HIV activity for the elected compound herein. Note that the instant method requires administering to a subject a therapeutically effective amount of a deprenyl compound. The prior art also teaches administering to a subject a deprenyl compound. Therefore the viral replication inhibition would be expected to have occurred in the prior art method. More specifically, the prior art teaches a method of treating viral infections by employing a deprenyl compound in therapeutic antiviral amounts. The prior art further teaches that the deprenyl compound is used in treating HIV particularly. Therefore as set forth in the obviousness rejection herein above the prior art suggests the employment of the elected deprenyl

compound herein in the instant method of treating HIV infection. The instant claims are directed to effecting a biochemical pathway, i.e., viral replication inhibition, with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
December 16, 2003

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

12/29/03